K130251
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Premarket Notification [510(k)] Summary
Esophagus bougie

The following information is provided following the format of 21 CFR 807.92.

MAR 13 2013

Submitter's Name:

Varian Medical Systems, Inc.
3120 Hansen Way C-260
Palo Alto, CA 94304

Contact Name: Peter J. Coronado
Phone: 650.424.5731
Fax: 650.842.5040
Date: December 2012

Proprietary Name: Varian Medical Systems, Inc. Esophagus bougie set

Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5700, Class II
Product Code: JAQ

Common/Usual Name: Varian Medical Systems, Inc. Esophagus bougie set

Predicate Device: Varian Esophagus bougie set

Device Description: The Varian Medical Esophagus Bougie is an HDR applicator designed to facilitate delivery of radiation to the Esophagus and has been modified to work with Varian Medical afterloaders. The bougie tube and catheter can be cleaned and disinfected with high level disinfectants and has a maximum insertion time of 24 hours. The clamping screw, bite protector and threaded ring can be steam sterilized. The fixation strap and guide wire are single use. The device does not contain any electronics or software.

A high activity radioactive source is placed within the applicator which has previously been placed for a specified clinical purpose in a patient.

The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into the applicator within the patient.

The length of time and position that the High Dose Rate source spends within the applicator is controlled in accordance with an Irradiation Treatment Prescription.

Intended Use Statement The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used in conjunction with a Varian high dose rate afterloader.

Indications for Use Statement The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used in conjunction with a Varian high dose rate afterloader.

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Technological Characteristics:

Significant change to the predicate device is listed below.

Performance	Cleared device	Device with change
Sterilization method: Bougie tube, catheter	Sterilized	Disinfected

The clamping screw, bite protector, threaded ring, fixation strap and guide wire sterilization remains the same.

Discussion of nonclinical testing:

The esophagus bougie sterilization efficacy and suitability of the manual cleaning and disinfection process was evaluated through design verification and testing. Non-clinical testing showed the test articles met the pre-defined acceptance criteria, thereby demonstrating the effectiveness of the cleaning and disinfection process plus the cleaning and disinfection agents according to DIN EN ISO 17664 (July 2004). Biocompatibility testing performed in accordance with ISO 10993-1, 10993-5 and 10993-10 show the device is safe for bodily contact.

Per the FDA's Guidance document **Deciding When to Submit a 510(k) for a Change to an Existing Device**, only the formulation of this non-implant PVC material was changed. One of the components used in the composite material is no longer available; however, the composite material remains the same. The reformulated material was evaluated through design verification and testing. Non-clinical testing showed the test articles met the pre-defined acceptance criteria, thereby demonstrating the reformulated material did not impact device performance or biocompatibility.

Conclusion of nonclinical testing:

The change to the esophagus bougie does not raise new questions of safety or effectiveness when compared to the predicate device and, therefore, is substantially equivalent to the predicate esophagus bougie.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Peter J. Coronado
Director, Varian Oncology Systems Regulatory Affairs
Varian Medical Systems, Inc.
911 Hansen Way, m/s E-110
PALO ALTO CA 94304-1038

Re: K130251
Trade/Device Name: Esophagus bougie
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: January 30, 2013
Received: February 7, 2013

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130251

Device Name: **Esophagus bougie**

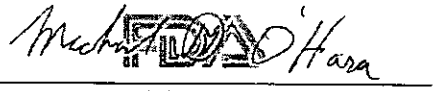
Indications for Use:

The Esophagus Bougie Set was designed to treat cancer of the esophagus. The Esophagus Bougie Set is an applicator used to facilitate delivery of a radiation source to the esophagus when used in conjunction with a high dose rate afterloader.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130251